UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,709	12/10/1999	RICHARD J. MELKER	U5583.0000/P	7980

24998 7590 06/21/2002

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L STREET NW
WASHINGTON, DC 20037-1526

EXAMINER
WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 06/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/457,709	Melker et al.
Examiner	**Art Unit**
Joseph Weiss	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 5, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *37-89* is/are pending in the application.

4a) Of the above, claim(s) *86-89* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *37-85* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *86-89* are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of claims 37-85 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the additional non-elected claims would not be a burden. This is not found persuasive because:

A. The MPEP section cited by applicant to support his arguments for keeping the claims of the two patently distinct inventions together is mere non-binding policy/guidance and cannot displace the binding statutory requirement of 35 USC 101 as interpreted by the case law that one patent is granted for one invention.

B. Even if the MPEP was found to supplant binding statutory requirements, while quantitative "volume" of claims is one way to measure "burden" this is not the only way to measure "burden." Applicant has admitted on the record that the two sets of claims present patently distinct inventions, which just so happen to reside in the same art field. However, the two sets of claims set forth completely distinct inventive concepts, which out side of this residence of a common art field, share no common technical features. In the instant situation an undue burden would be placed upon the examiner because he would have to juggle/track/search/analyze two completely different inventive concepts, thus meeting the standards of the policy/guidance of the relevant MPEP sections rendering restriction/election permissible.

Therefore, the requirement is still deemed proper and is therefore made FINAL. Accordingly, a complete reply to this rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)) to include current/final disposition, e.g. the patent number of the issued parent application.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested:

"Patient Ventilatory Method Utilizing Height Based Ventilatory Parameter Calculations"

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 37-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka (US 5042470) in view of Heinonen (US 5649531) & Haluszka et al, "Whole Body Plethysmography".

In regards to claims 37-85 Kanesaka substantially discloses the instant application's claimed invention to include the provision of a ventilator system (1/5) that contains a control device (Col. 4 lines 15-32, note the teaching of inputting of patient data into device that will facilitate ventilation, i.e. to control the device, therefore one of ordinary skill in the art would reasonably conclude that the device has a means for controlling its operation), with a means for inputting a data (note col. 4 lines 17-20) that provides ventilation to a patient and that calculates ventilatory parameters utilizing such data which includes data that only represents height (i.e. does not put in a mixed variable such as patient surface area based upon height & weight), but does not explicitly disclose that the data is input in the raw form and that the control device renders the calculation of such data into the necessary ventilatory parameters. However, Heinonen discloses such raw data input with the control device rendering the respiratory ventilation control values (col. 8 lines 19-40). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Heinonen and used them with the device of Kanesaka. The suggestion/motivation for doing so would have been to relieve the operator of the burden of rendering the calculations and also minimizing the potential for human error by having the control device execute the calculations instead of the operator.

Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

While the current claim language is open and does not include a negative limitation that exclusively limits the data input to only patient height, upon which all ventilatory calculations are based upon, if in the event this is applicant's intent, if such a limitation is intended the suggested device of substantially discloses the instant application's claimed invention, but does not explicitly disclose this exclusivity of using only patient height. However, Haluszka disclose such (See the 5th paragraph on the first page of the English language abstract that starts with "It was stated") The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Haluszka and used them with the suggested device. The suggestion/motivation for doing so would have been to because patient body length alone can function as a sufficient ventilatory parameter/limitation predictor and all other raw data patient inputs improve correlation very little or are without practice influence (See paragraph 5 of the English language abstract of Haluszka). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of

mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Claims 38-47 define a plurality of ventilation parameters which are disclosed by Kanesaka (note col. 4 lines 15-32) as modified by Heinonen and/or Haluszka (note the tables and materials/methods sections) and/or such parameters would be mere obvious variables that one of ordinary skill in the art would appreciate as necessary to carry out any ventilatory methodology.

The balance of the claims 48-85 appear to be substantially equivalent in scope to claims 37-47 and are therefore rejected by the suggested device of Kanesaka, Heinonen & Haluszka as noted above which is herein incorporated by reference. With respect to the alarms of claim 66 and those claims that set forth the calculation/determination of a "ventilatory limit" note Kanesaka (Col. 4, line 5 et seq) which teaches a plurality of alarms which are responsive to the manually set ventilation parameters disclosed at col. 4, lines 16 et seq; these same parameters of the suggested device of Kanesaka, Heinonen & Haluszka are readable upon applicant's set forth "ventilatory limits" as one of ordinary skill in the art would appreciate such limits to be merely the points of the derived values wherein safe/proper ventilation wold not be affected and as such the operator/user should be notified and the control should respond/adjust ventilation.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 37-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6000396. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth a method of operating a ventilator that includes the steps of providing a ventilator with a control device having an input means, inputting into the control device data representing only body length of a patient, calculating within the control device at least one ventilation parameter.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5752509, 5546933, 5535739, 5490502, 5400777, 5183038, 5092326, 4326513

EPO - 1060755, 0776671, 0753320

Morton et al, Spirometric Values for Normal Perth Children aged Six to Twelve Years.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Aaron Lewis, can be reached at telephone number (703) 308-0716. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

JFweiss

June 14, 2002

DENNIS RUHL
PRIMARY EXAMINER